



NDA 20-723/S-001

3M Pharmaceuticals  
Attention: Mark A. Morken, R.Ph  
Senior Regulatory Associate  
3M Center, Building 270-3A-08  
St. Paul, Minnesota 55144-1000

Dear Mr. Morken:

Please refer to your supplemental new drug application dated April 4, 1997, received April 7, 1997 submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Aldara (imiquimod) Cream, 5%.

We acknowledge receipt of your submissions dated April 28, 1997 and dated August 23, 2001.

This supplemental new drug applications provides for the revision of the Pharmacodynamics subsection under the Clinical Pharmacology section.

We have completed the review of this supplemental applications as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed agreed upon labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-723/S-001." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Practitioner” letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

*{See appended electronic signature page}*

Jonathan K. Wilkin, M.D.  
Director  
Division of Dermatologic & Dental Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Jonathan Wilkin  
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